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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB (collectively "Plaintiffs" or "AstraZeneca") bring this action for patent infringement against Teva Pharmaceuticals USA, Inc. ("Teva").

THE PARTIES

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850, U.S.A.

2. Plaintiff AstraZeneca UK Limited is a private limited company organized under the laws of England and Wales, with its registered office at 2 Kingdom St., London W2 6BD, United Kingdom.

3. Plaintiff AstraZeneca AB is a public limited liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

4. On information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva maintains a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, U.S.A.

5. On information and belief, Teva is in the business of manufacturing, marketing, and selling branded and generic copies of branded pharmaceutical products throughout the United States, including within this District.

6. On information and belief, Teva filed New Drug Application ("NDA") No. 210063 seeking regulatory approval from the U.S. Food and Drug Administration ("FDA") to market and sell a proposed Fulvestrant Injection, 250 mg/5ml (50 mg/ml) product throughout the United States, including within this District.

NATURE OF THE ACTION

7. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Teva's filing of NDA No. 210063 with the FDA.

8. Teva is seeking approval to engage in the commercial manufacture, use and sale of a proposed Fulvestrant Injection, 250 mg/5ml (50 mg/ml) product (the "Proposed NDA Product") prior to the expiration of AstraZeneca's U.S. Patent Nos. 6,774,122, 7,456,160, 8,329,680, and 8,466,139.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Teva because Teva has maintained continuous and systematic contacts with the State of New Jersey and this District.

11. On information and belief, Teva markets and sells brand and generic pharmaceutical products throughout the United States, including in the State of New Jersey, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, brand and generic pharmaceutical products. Teva derives substantial revenue from goods used or consumed or services rendered in this judicial district.

12. More specifically, this Court has personal jurisdiction over Teva by virtue of its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial, continuous, and systematic contacts with the State of New Jersey. On information and belief, Teva: (1) is registered with the State of New Jersey Division of Revenue and Enterprise Services and maintains a Business Registration Certificate under entity identification number 0100250184; (2) is registered with the New Jersey Department of Health Food and Drug Safety Program as a manufacturer and wholesale drug establishment and

maintains a Drug and Medical Device Certificate of Registration under Registration No. 5000583; (3) is registered with the New Jersey Department of Health Food and Drug Safety Program as a wholesale drug establishment and maintains a Drug and Medical Device Certificate of Registration under Registration No. 5003436; (4) maintains a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, U.S.A; (5) specifically, Joyce Delgaudio, Executive Director, Regulatory Affairs, whose office is located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, U.S.A, is the U.S. Agent for the manufacturer of the Proposed NDA product; (6) intentionally markets and provides its brand and generic pharmaceutical products to residents of this State; and (7) enjoys substantial income from this State.

13. On information and belief, Teva intends to distribute and sell its Proposed NDA Product in this judicial district.

14. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

THE PATENTS-IN-SUIT

15. United States Patent No. 6,774,122 (the "'122 Patent"), entitled "Formulation," was duly and legally issued on August 10, 2004 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '122 Patent. AstraZeneca UK Limited is the beneficial owner of the '122 Patent. A copy of the '122 Patent is attached as **Appendix A**.

16. United States Patent No. 7,456,160 (the "'160 Patent"), entitled "Formulation," was duly and legally issued on November 25, 2008 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is

the legal owner of the ’160 Patent. AstraZeneca UK Limited is the beneficial owner of the ’160 Patent. A copy of the ’160 Patent is attached as **Appendix B**.

17. United States Patent No. 8,329,680 (the “’680 Patent”), entitled “Formulation,” was duly and legally issued on December 11, 2012 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the ’680 Patent. AstraZeneca UK Limited is the beneficial owner of the ’680 Patent. A copy of the ’680 Patent is attached as **Appendix C**.

18. United States Patent No. 8,466,139 (the “’139 Patent”), entitled “Formulation,” was duly and legally issued on June 18, 2013 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the ’139 Patent. AstraZeneca UK Limited is the beneficial owner of the ’139 Patent. A copy of the ’139 Patent is attached as **Appendix D**.

FACTUAL BACKGROUND

FASLODEX® (fulvestrant) intramuscular injection

19. FASLODEX® (fulvestrant) intramuscular injection is an estrogen receptor antagonist approved by the FDA for the treatment of: (a) hormone receptor positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy; and (b) hormone receptor positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression following endocrine therapy.

20. FDA regulatory exclusivity for the treatment of hormone receptor positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression following endocrine therapy will expire on February 19, 2019.

21. AstraZeneca UK Limited is the holder of approved New Drug Application ("NDA") No. 21-344 for FASLODEX® (fulvestrant) intramuscular injection, in 50 mg/mL dosage forms. AstraZeneca Pharmaceuticals LP is the authorized agent for matters related to NDA No. 21-344 in the United States.

22. The use of FASLODEX® (fulvestrant) intramuscular injection is covered by one or more Claims of the '122, '160, '680, and '139 Patents.

23. The '122, '160, '680, and '139 Patents have been listed for NDA No. 21-344 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

24. AstraZeneca Pharmaceuticals LP sells and distributes FASLODEX® (fulvestrant) intramuscular injection in the United States pursuant to NDA No. 21-344.

TEVA'S NDA

25. By Notice Letter dated February 27, 2017, Teva notified AstraZeneca that Teva's NDA No. 210063 was submitted to the FDA and that Teva is seeking approval to engage in the commercial manufacture, use and sale of the Proposed NDA Product prior to the expiration of the '122, '160, '680, and '139 Patents, and included within NDA No. 210063 a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) ("Paragraph IV Certification") that the '122, '160, '680, and '139 Patents will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed NDA Product.

26. Teva was aware of the Patents-in-Suit when NDA No. 210063 was filed with a Paragraph IV Certification.

27. The Notice Letter contained no allegations that the Claims of the '122, '160, '680 and '139 Patents are invalid or unenforceable.

28. The Notice Letter contains one narrow allegation of non-infringement, but does not otherwise deny: (a) that the Proposed NDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '122, '160, '680, and '139 Patents under 35 U.S.C. § 271(a); or (b) that Teva will actively induce and/or contribute to infringement by others of one or more Claims of the '122, '160, '680, and '139 Patents under 35 U.S.C. § 271(b) and/or (c).

29. On information and belief, NDA No. 210063 refers to and relies upon Plaintiffs' FASLODEX® (fulvestrant) intramuscular injection NDA.

30. On information and belief, the Proposed NDA Product will have instructions for use that substantially copy the instructions for FASLODEX® (fulvestrant) intramuscular injection, including instructions for administering the Proposed NDA Product by intramuscular injection to treat hormone dependent breast cancer. The instructions accompanying the Proposed NDA Product will induce others to use and/or contribute to others' use of the Proposed NDA Product in the manner set forth in the instructions.

31. On information and belief, based on Teva's assertions to the FDA, every limitation of the patent claims is met by Teva's Proposed NDA Product with its instructions, either literally or by equivalents by performing substantially the same function, in substantially the same way, to obtain substantially the same results; any difference is insubstantial.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,774,122

32. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 31 of this Complaint.

33. The use of the Proposed NDA Product is covered by one or more Claims of the ’122 Patent.

34. Teva’s submission of NDA No. 210063 under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product before the expiration of the ’122 Patent constitutes infringement of one or more Claims of the ’122 Patent under 35 U.S.C. § 271(e)(2).

35. On information and belief, Teva plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product immediately upon approval of NDA No. 210063 and will direct physicians and patients on the use of the Proposed NDA Product through product labeling.

36. The Proposed NDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the ’122 Patent under 35 U.S.C. § 271(a).

37. Upon FDA approval of NDA No. 210063, Teva will infringe the ’122 Patent by making, using, offering to sell, selling, and/or importing the Proposed NDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

38. Teva had knowledge of the ’122 Patent when it submitted NDA No. 210063 to the FDA and Teva knows or should have known that it will aid and abet another’s direct infringement of at least one of the Claims of the ’122 Patent.

39. As discussed above in paragraphs 27-31, the Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the ’122 Patent.

40. Teva had knowledge of the '122 Patent and is knowingly and willfully infringing the '122 Patent.

41. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

42. On information and belief, Teva lacked a good faith basis for alleging non-infringement of the '122 Patent when it filed its Paragraph IV Certification. Accordingly, Teva's Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,774,122

43. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 42 of this Complaint.

44. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

45. On information and belief, Teva has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of the '122 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after NDA No. 210063 is approved.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,456,160

46. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 45 of this Complaint.

47. The use of the Proposed NDA Product is covered by one or more Claims of the ’160 Patent.

48. Teva’s submission of NDA No. 210063 under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product before the expiration of the ’160 Patent constitutes infringement of one or more Claims of the ’160 Patent under 35 U.S.C. § 271(e)(2).

49. On information and belief, Teva plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product immediately upon approval of NDA No. 210063 and will direct physicians and patients on the use of the Proposed NDA Product through product labeling.

50. On information and belief, the Proposed NDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the ’160 Patent under 35 U.S.C. § 271(a).

51. Upon FDA approval of NDA No. 210063, Teva will infringe the ’160 Patent by making, using, offering to sell, selling, and/or importing the Proposed NDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

52. Teva had knowledge of the ’160 Patent when it submitted NDA No. 210063 to the FDA and Teva knows or should have known that it will aid and abet another’s direct infringement of at least one of the Claims of the ’160 Patent.

53. As discussed above in paragraphs 27-31, the Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the ’160 Patent.

54. Teva had knowledge of the ’160 Patent and is knowingly and willfully infringing the ’160 Patent.

55. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

56. On information and belief, Teva lacked a good faith basis for alleging non-infringement of the ’160 Patent when it filed its Paragraph IV Certification. Accordingly, Defendant’s Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,456,160

57. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 56 of this Complaint.

58. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

59. On information and belief, Teva has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of the ’160 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after NDA No. 210063 is approved.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 8,329,680

60. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 59 of this Complaint.

61. The use of the Proposed NDA Product is covered by one or more Claims of the ’680 Patent.

62. Teva's submission of NDA No. 210063 under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product before the expiration of the '680 Patent constitutes infringement of one or more Claims of the '680 Patent under 35 U.S.C. § 271(e)(2).

63. On information and belief, Teva plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product immediately upon approval of NDA No. 210063 and will direct physicians and patients on the use of the Proposed NDA Product through product labeling.

64. On information and belief, the Proposed NDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '680 Patent under 35 U.S.C. § 271(a).

65. Upon FDA approval of NDA No. 210063, Teva will infringe the '680 Patent by making, using, offering to sell, selling, and/or importing the Proposed NDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

66. Teva had knowledge of the '680 Patent when Teva submitted NDA No. 210063 to the FDA and Teva knows or should have known that it will aid and abet another's direct infringement of at least one of the Claims of the '680 Patent.

67. As discussed above in paragraphs 27-31, the Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the '680 Patent.

68. Teva has knowledge of the '680 Patent and is knowingly and willfully infringing the '680 Patent.

69. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

70. On information and belief, Teva lacked a good faith basis for alleging non-infringement of the '680 Patent when it filed its Paragraph IV Certification. Accordingly, Teva's Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,329,680

71. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 70 of this Complaint.

72. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

73. On information and belief, Teva has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of the '680 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after NDA No. 210063 is approved.

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 8,466,139

74. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 73 of this Complaint.

75. The use of the Proposed NDA Product is covered by one or more Claims of the '139 Patent.

76. Teva's submission of NDA No. 210063 under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale

and/or offer for sale of the Proposed NDA Product before the expiration of the '139 Patent constitutes infringement of one or more Claims of the '139 Patent under 35 U.S.C. § 271(e)(2).

77. On information and belief, Teva plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product immediately upon approval of NDA No. 210063 and will direct physicians and patients on the use of the Proposed NDA Product through product labeling.

78. On information and belief, the Proposed NDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '139 Patent under 35 U.S.C. § 271(a).

79. Upon FDA approval of NDA No. 210063, Teva will infringe the '139 Patent by making, using, offering to sell, selling, and/or importing the Proposed NDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

80. Teva had knowledge of the '139 Patent when it submitted NDA No. 210063 to the FDA and Teva knows or should have known that it will aid and abet another's direct infringement of at least one of the Claims of the '139 Patent.

81. As discussed above in paragraphs 27-31, the Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the '139 Patent.

82. Teva has knowledge of the '139 Patent and is knowingly and willfully infringing the '139 Patent.

83. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

84. On information and belief, Teva lacked a good faith basis for alleging non-infringement of the '139 Patent when it filed its Paragraph IV Certification. Accordingly, Teva's Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,466,139

85. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 84 of this Complaint.

86. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

87. On information and belief, Teva has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of the '139 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after NDA No. 210063 is approved.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

a) Judgment that Teva's submission of NDA No. 210063 was an act of infringement of one or more Claims of the '122, '160, '680, and '139 Patents under 35 U.S.C. § 271(e)(2);

b) Judgment that Teva's making, using, offering to sell, selling, or importing into the United States of the Proposed NDA Product prior to the expiration of the '122, '160, '680, and '139 Patents, will directly infringe, will actively induce infringement, and/or will contribute to the infringement of one or more Claims of the '122, '160, '680, and/or '139 Patents;

c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of NDA No. 210063 shall be a date that is not earlier than the expiration of the '122, '160, '680, and '139 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

d) An Order permanently enjoining Teva, its affiliates and subsidiaries, each of its officers, agents, servants and employees, and any person acting in concert with Teva, from making, using, offering to sell, selling, marketing, distributing, or importing into the United States the Proposed NDA Product until after the expiration of the '122, '160, '680, and '139 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

e) Judgment declaring that infringement, inducement or contributory infringement of the '122, '160, '680, and/or '139 Patents by Teva is willful should Teva commercially manufacture, use, offer to sell, sell, or import into the United States the Proposed NDA Product;

f) A declaration that this case is an exceptional case within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

g) Plaintiffs' reasonable costs and expenses in this action; and

h) Such further and other relief as this Court deems proper and just.

Dated: April 10, 2017

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter of the following actions:

- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. SANDOZ INC., and SANDOZ INTERNATIONAL GmbH*, C.A. No. 1:14-cv-03547-RMB-KMW ("*AstraZeneca v. Sandoz*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. SAGENT PHARMACEUTICALS, INC.*, C.A. No. 1:14-cv-05539-RMB-KMW ("*AstraZeneca v. Sagent*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. GLENMARK PHARMACEUTICALS INC., USA*, C.A. No. 1:15-cv-00615-RMB-KMW ("*AstraZeneca v. Glenmark*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. AGILA SPECIALTIES, INC. F/K/A STRIDES INC., ONCO THERAPIES LIMITED, MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC.*, C.A. No. 1:15-cv-06039-RMB-KMW ("*AstraZeneca v. Agila*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC.*, C.A. No. 1:15-cv-07009-RMB-KMW ("*AstraZeneca v. Mylan*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. TEVA PHARMACEUTICALS USA, INC.*, C.A. No. 1:15-cv-07889-RMB-KMW ("*AstraZeneca v. Teva*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. INNOPHARMA, INC.*, C.A. No. 1:16-cv-00894-RMB-KMW ("*AstraZeneca v. InnoPharma Inc.*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. INNOPHARMA LICENSING LLC*, C.A. No. 1:16-cv-01962-RMB-KMW ("*AstraZeneca v. InnoPharma Licensing*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. MYLAN INSTITUTIONAL LLC*, C.A. No. 1:16-cv-04612-RMB-KMW ("*AstraZeneca v. Mylan Institutional*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.*, C.A. No. 1:17-cv-00926-RMB-KMW ("*AstraZeneca v. Dr. Reddy's*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. AMNEAL PHARMACEUTICALS LLC*, C.A. No. 1:17-cv-01968-RMB-KMW ("*AstraZeneca v. Amneal*")

The foregoing cases involve AstraZeneca's FASLODEX® (fulvestrant) intramuscular

injection product. The FASLODEX® (fulvestrant) intramuscular injection cases have been assigned to Hon. Renée M. Bumb, U.S.D.J. The *AstraZeneca v. Sandoz*, *AstraZeneca v. Sagent*, and *AstraZeneca v. Glenmark* cases were consolidated by Judge Bumb under lead case, *AstraZeneca Pharms. LP, et al. v. Sandoz Inc., et al.*, Civ. No. 14-cv-03547. The *AstraZeneca v. Agila*, *AstraZeneca v. Mylan*, *AstraZeneca v. Teva*, *AstraZeneca v. Mylan Institutional*, and *AstraZeneca v. InnoPharma Licensing* cases were consolidated by Judge Bumb under Consolidated Case No. 1:15-cv-06039. To date, the following cases have been terminated: *AstraZeneca v. Sandoz*, *AstraZeneca v. Sagent*, *AstraZeneca v. Glenmark*, *AstraZeneca v. InnoPharma Inc.*, *AstraZeneca v. Agila*, *AstraZeneca v. Mylan*, *AstraZeneca v. Mylan Institutional*, and *AstraZeneca v. Dr. Reddy's*. The following cases remain pending before Judge Bumb: *AstraZeneca v. Teva* and *AstraZeneca v. InnoPharma Licensing* (continuing under lead case, *AstraZeneca Pharms. LP, et al. v. Agila Specialties, Inc., et al.*, Civ. No. 15-cv-06039 (Consolidated)) and *AstraZeneca v. Amneal* (Civ. No. 1:17-cv-01968). Plaintiffs respectfully request that this case likewise be assigned to Judge Bumb due to her familiarity with the subject matter.

Dated: April 10, 2017

Respectfully submitted,

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